

**REMARKS**

The Office Action mailed December 21, 2007 has been carefully reviewed and the following remarks are made in response thereto. Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Claims 11-12, 17-67 are pending. As a result of restriction and elections, claims 17-20 and 32-66 have been withdrawn<sup>1</sup>. Claims 13-16 have been cancelled. Claims 11 and 17-20 have been amended. Claim 67 has been added. Support for the amendment to claim 11 and new claim 67 can be found on page 4 of the specification. Applicants respectfully submit that no prohibited new matter has been added by amendment.

**I. Summary of the Office Action**

1. Claims 11-12 and 17-67 will be pending upon entry of the attached amendment.
2. The Examiner maintained the species election requirement. The requirement was made final.
3. The Examiner rejected claims 11-16, 21-22, and 30-31 under 35 U.S.C. 102(e) as being anticipated by Vande-Velde, U.S. PG Patent No. 20040013695.
4. The Examiner rejected claims 23-25 under 35 U.S.C. 103(a) as allegedly being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Martin *et al.*, U.S. PG Patent No. 20030049271.
5. The Examiner rejected claims 23 and 26-29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Kricek, *et al.*, U.S. Patent No. 6,610,297.

---

<sup>1</sup> Applicants note that claims 17 to 20 have been amended and request entering of the amendment in the event that Applicants' concurrently filed Petition to the Director Under 37 C.F.R. §§ 1.144 and 1.181 to Withdraw Final Restriction Requirement is granted.

6. The Examiner provisionally rejected claims 11-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/469,162 in view of Vande-Velde.

7. The Examiner provisionally rejected claims 11-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 89 of copending Application No. 10/490,920 in view of Vande-Velde.

8. No claims were allowed.

## **II. Response to the Office Action**

### **1. Election**

The Examiner maintained the species election requirement with respect to Antacids, H<sub>2</sub>-receptors, and Proton Pump Inhibitors and withdrew claims 17-20 and 32-66. The requirement was made final. Applicant is concurrently filing a petition requesting the withdrawal of the species election requirement.

### **2. Claim Rejection under § 102**

The Examiner rejected claims 11-16, 21-22, and 30-31 under 35 U.S.C. 102(e) as being anticipated by Vande-Velde, U.S. PG Patent No. 20040013695. Applicants respectfully traverse the rejection.

Claim 11 has been amended to recite a gastric acid reducing substance, wherein the gastric acid reducing substance is selected from the group consisting of antacids which act protectively through the mucous membrane, H<sub>2</sub>-receptor agonists and proton pump inhibitors.

Antacids perform a neutralization reaction, i.e. they buffer gastric acid, raising the pH to reduce acidity in the stomach. The antacids described in Vande-Velde are limited to this type. Specifically Vande-Velde at paragraph [0006] states:

In another aspect of the present invention the oral vaccine quick dissolving cake comprises an antacid. The antacid being such that when dissolved in saliva, and swallowed, it is capable of raising the pH of the stomach contents such that the vaccine antigen is not substantially degraded in the stomach. Most preferably the antacid is water insoluble and also acts as an adjuvant, in addition it is more

preferred that when antigen is adsorbed to the surface of the insoluble antacid/adjuvant the antigen is protected from stomach acid.

The primary purpose of the antacids of Vande-Velde are to raise the pH of the stomach to avoid degradation of the proteinaceous antigens. Vande-Velde does not teach the class of antacids of the amended claims, namely antacids that act protectively through the mucous membrane.

In contrast, antacids which act protectively through the mucous membrane, such as sucralfate and carbenoxolone (paragraph [0016], [0035]), are characterized by a different mode of action. The predominant feature of sucralfate, for example, is a protection of the mucosa from endogenous and exogenous noxious agents. These cytoprotective properties result from a locally formed layer covering ulcers and erosions which inhibits the diffusion of H-ions and pepsin to the damaged mucosa. This layer is also stable against exogenous substances with deleterious effects on the mucosa like alcohol and salicylates. Furthermore, sucralfate binds pepsin and bile acids. Sucralfate also has a stimulating effect on the release of prostaglandins and the regeneration of epithelial cells in the gastric mucosa has been demonstrated. ***Furthermore, there is no influence of sucralfate on the production of gastric juice and pH.*** Because Vande-Velde does not teach the class of antacids of the amended claims, namely antacids that act protectively through the mucous membrane, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §102(e).

### **3. Claim Rejections under § 103**

The Examiner rejected claims 23-25 under 35 U.S.C. 103(a) as allegedly being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Martin *et al.*, U.S. PG Patent No. 20030049271. The Examiner also rejected claims 23 and 26-29 under 35 U.S.C. 103(a) as allegedly being unpatentable over Vande-Velde, as applied to claims 11-12 and 21-22, in view of Kricek, *et al.*, U.S. Patent No. 6,610,297. Applicants respectfully traverse the rejection.

Claim 11 has been amended to recite a gastric acid reducing substance, wherein the gastric acid reducing substance is selected from the group consisting of antacids which act protectively through the mucous membrane, H<sub>2</sub>-receptor agonists and proton pump inhibitors.

Neither Vande-Velde, Martin *et al.*, nor Kricek *et al.* teach or suggest the claimed antacid. Specifically, Martin *et al.*, and Kricek *et al.* do not teach an antacid which act protectively through the mucous membrane. Martin *et al.* and Kricek *et al.* do not remedy this insufficiency, therefore Vande-Velde in combination with Martin *et al.* and Kricek *et al.* do not teach each and every element of the claims rejected in the instant rejection. For these reasons, Applicant withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

#### **4. Double Patenting**

The Examiner provisionally rejected claims 11-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 14 of copending Application No. 10/469,162 in view of Vande-Velde. The Examiner also provisionally rejected claims 11-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 89 of copending Application No. 10/490,920 in view of Vande-Velde. Applicants respectfully traverse the rejection.

Claim 11 has been amended to recite a gastric acid reducing substance, wherein the gastric acid reducing substance is selected from the group consisting of antacids which act protectively through the mucous membrane, H<sub>2</sub>-receptor agonists and proton pump inhibitors.

Neither Vande-Velde, U.S. Application 10/469,162, nor U.S. Application No. 10/490,920 teach or suggest the claimed antacid. Specifically, U.S. Application 10/469,162, nor U.S. Application No. 10/490,920 do not teach an antacid which acts protectively through the mucous membrane. U.S. Application 10/469,162 and U.S. Application No. 10/490,920 do not remedy this insufficiency, therefore Vande-Velde in combination with U.S. Application 10/469,162, or U.S. Application No. 10/490,920 do not teach each and every element of the claims rejected in the instant rejection. For these reasons, Applicant withdrawal of the rejection under 35 U.S.C. § 103(a) as to the remaining amended claims is respectfully requested.

**III. Conclusion**

Applicant believes that the above-referenced application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections and early notice of allowance to that effect is respectfully requested.

**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 13-3250, reference No. 37488.00400. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

If the Examiner finds that a telephone conference would further prosecution of this application, the Examiner is invited to contact the undersigned at 202-835-7553.

Respectfully submitted,

**MILBANK, TWEED, HADLEY & MCCLOY LLP**

Dated: March 21, 2008

*allison fulton REG. NO. 57,106*  
Einar Stole  
Reg. No. 47,272

**Customer No. 000038647**  
**Milbank, Tweed, Hadley & McCloy LLP**  
International Square Building  
1850 K Street, N.W., Suite 1100  
Washington, D.C. 20006  
Telephone: (202) 835-7525  
Facsimile: (202) 263-7525